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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	PAPER NUMBER
3762	
MAIL DATE	DELIVERY MODE
03/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/804,560	HAREL ET AL.	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-55,79-85,87 and 101-123* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52-55,79-85,87 and 101-123* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/3/2010 has been entered.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 and 365(c) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application Nos. PCT/IL03/00736, US 10/237,263, PCT/IL00/00566, US 09/914,889, PCT/IL00/00132, and US 60/123,532, fail to provide adequate support or enablement in the manner provided by

the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The Examiner was unable to find support for the combination of an electrode mounted attached to muscle tissue and electrifying that electrode in a manner suitable for blood glucose level control, wherein the manner includes a pulse train having the claimed ranges of signal parameters, as required by all pending claims. For instance, Applicant appears to rely on the embodiment drawn to a mesh electrode on the pancreas and a needle ground electrode inserted into the abdominal muscle wall (*e.g.*, page 26) to support the electrode limitations. However, the examiner was unable to locate, in any of the priority documents, disclosure that this electrode configuration is used with the signal parameters disclosed for stomach or intestine stimulation. This appears to be a mixing of embodiments. Furthermore, the examiner was unable to find support for the claimed ranges of pulse width and pulse train duration. Disclosure of species within the claimed ranges does not provide written description support for the claimed ranges. If applicant asserts that such written description support is present in the priority documents, the examiner respectfully requests citation by document and page number.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 52-55, 79-85, 87, and 101-123 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner was unable to find support in the originally-filed disclosure for the combination of claim elements including the following:

5. In regards to claim 52, the support for the electrode limitations asserted by applicant are drawn to the embodiment of a mesh electrode on the pancreas and a needle ground electrode inserted into the abdominal muscle wall (*e.g.*, page 26). However, the examiner was unable to locate disclosure that this electrode configuration is used with the signal parameters disclosed for stomach or intestine stimulation. This appears to be a mixing of embodiments. Furthermore, the examiner was unable to find support for the claimed ranges of pulse width and pulse train duration. For example, page 45 discloses that the pulse width can be 1ms to 1s, but does not support the currently claimed range of "at least 1 millisecond." Lastly, the disclosure appears to indicate that a single pulse can be "2 or 20 seconds long," but does not appear to disclose that this refers to a train of pulses, or that the train of pulses is "shorter than 20 seconds," as currently claimed.

6. In regards to claim 53, the examiner was able to find written description support for a system to "overstimulate" in case of "doubt," open-loop control (page 43), and "semi-open-loop control" (page 43), which appears to be closed loop control with infrequent feedback. However, none of these concepts appear to provide support for claim 53's discussion of "desired" glucose levels and "certainty," because there appears

to be no description of circuitry that can determine levels of "certainty" or who or what "desires" the various levels.

7. In regards to claim 79, "without mediation of insulin" appears to lack support. Although mediation of glucagon would appear to be a "non-insulin" manner, the disclosure appears to lack preclusion of both glucagon ("non-insulin") and insulin being mediated.

8. In regards to claims 106, 107, 110, 111, 113-118, 120, and 121, the limitations appear to be drawn to the embodiment wherein the electrode is attached to the stomach or intestine. However, applicant appears to rely on the "needle ground electrode in the abdominal wall" embodiment for support of claim 52. This appears to be an unsupported mixing of embodiments.

9. In regards to claim 115, the examiner was unable to find support for the claimed range of "at least 15 minutes."

10. In regards to claim 116, the examiner was unable to find support for the claimed range of "at least 0.5 seconds" or "for at least 5 such detections."

11. In regards to claim 117, the examiner was unable to find support for the claimed range of "at least 20 seconds."

12. In regards to claim 118, the examiner was unable to find support for the claimed range of "less than 10 seconds."

13. In regards to claim 119, the examiner was unable to find support for stimulation that "does not affect nervous tissue." Any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is

not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement (See MPEP 2173.05(i)).

14. In regards to claim 120, the examiner was unable to find support for electrification of the electrode "also in a manner which paces said stomach."

15. In regards to claim 121, the examiner was unable to find support for stimulation that "does not cause propagation of an action potential in said stomach or a pancreas." Any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement (See MPEP 2173.05(i)).

16. Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim recites closing a loop to a "desired" blood glucose level using electrical stimulation, and "stimulating more than necessary for achieving a desired blood glucose modification" if the system does not indicate "with certainty" that the desired modification was achieved. Based on the sparse guidance provided by the prior art and Applicant at,

e.g., page 22 of "over stimulat[ing] in cases of doubt," the lacking description of examples using this algorithm, and the breadth of the claim, the examiner respectfully asserts that practicing this invention would require undue experimentation. See MPEP § 2164.01(a). For instance, how does the circuitry know whether it is "certain" about achievement of glucose modification or not? It appears that the system measures a blood glucose level with a sensor, but it is not clear how or if the system can acquire this level and then determine whether or not the circuitry is "certain" or uncertain whether this level is correct. If the system is stimulating more than necessary for the desired modification, does this not just mean that the increased modification is the "desired" level, and the lower level is merely arbitrary? For example, if the medical literature indicates that 100 mg/dl of glucose is normal/desired, would merely setting the threshold to 120 mg/dl if the device is not "certain" be sufficient to meet the limitations of the claim? In that case, is the 120 mg/dl level now just the "desired" level?

17. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

18. Claims 53, 104, 107, 111, 122, and 123 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

19. In regards to claim 53, it is unclear whether the "a desired" limitation of line 2, "a desired" limitation of line 6, and "said desired" limitation of the last line refer to the same "desired" level, or different ones. Also it is unclear who or what "desires" the glucose

levels (*i.e.*, whether the levels are programmed in a memory or some subjective desire of some user or patient). Further, "a sensor" is inferentially included, rendering it unclear whether this element is part of the claimed invention. It is suggested to positively recite the element before indicating that the circuitry uses the element.

20. In regards to claim 104, it is unclear what element of the system the claim limits.

21. In regards to claim 107, it is unclear as to what "local" refers (*i.e.*, local to what?).

22. In regards to claim 111, "said electrodes" are lacking antecedent basis because only one electrode has been set forth.

23. In regards to claim 115, it is unclear whether the system requires a sensor, or whether the circuitry merely requires an input for a sensor.

24. In regards to claim 116, nothing has been set forth to detect an action potential, rendering it unclear what element or elements of the system carry out this function.

25. In regards to claim 122, "a digestion sensor" is inferentially included. It is suggested to positively recite the element before indicating that the circuitry uses it.

26. In regards to claims 109 and 123, it is unclear what element the claim limits. It is suggested to recite the circuitry electrifying the electrode in such a manner.

Claim Rejections - 35 USC § 101

27. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

28. Claim 113 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 113 positively recites that the electrode is sutured to part of the human body, inferentially including the human body in the claim.

It is suggested to functionally recite the electrode as being "adapted to" or "configured to" be attached to said muscle.

Claim Rejections - 35 USC § 102

29. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

30. Claims 52-55, 79-85, 87, 101-112, 114, 115, and 120-123 are rejected under 35 U.S.C. 102(b) as being anticipated by Wernicke et al. (US 5,231,988, hereinafter "Wernicke").

31. In regards to claims 52, 87, 106, 110, and 111, Wernicke discloses an apparatus for blood glucose control (abstract) comprising an implantable electrode capable of being mounted attached to muscle tissue in the abdominal cavity (col. 5, line 68 to col. 6, line 3 and col. 7, lines 13-29) and circuitry that electrifies the electrode in a manner suitable for blood glucose level control (abstract), said manner including at least one pulse train wherein each pulse is at least 1ms long and wherein the train is shorter than 20 seconds (Table II). Wernicke's disclosure that the electrode is implanted "at or near the stomach" is an implicit disclosure that the electrode is "mounted attached to muscle tissue," albeit indirectly, by virtue of the innervation of the vagus into the muscle tissue

at the stomach, and the electrode 10 (conductive housing). Additionally and alternatively, Wernicke's electrode is necessarily capable of being mounted attached to stomach, duodenum muscle tissue, or any other nearby anatomical structure by, *e.g.*, suturing the electrode in place on muscle tissue in the abdominal cavity, as disclosed by Applicant on pages 56 and 57 of the specification.

32. In regards to claim 53, the device is a closed-loop system (col. 7, lines 30-67) that stimulates more than necessary for achieving a desired effect of electrification (wherein the "desired" effect is lowering glucose by even the slightest bit - less than necessary to return glucose levels to "normal levels"), when the sensed effect does not indicate with certainty that the electrification was sufficient or insufficient (the sensor never indicates "with certainty" because there is necessarily a certain level of imprecision and inaccuracy in real-world sensors).

33. In regards to claim 54, the circuitry is semi-open loop where a relatively long stimulation series is applied without feedback to return glucose to a normal level (col. 9, lines 41-50).

34. In regards to claim 55, the system is an open loop system (col. 9, lines 51-55).

35. In regards to claim 82, the apparatus is programmed with information pertaining to slow-acting chemical-based insulin therapy provided to a pancreas (col. 8, lines 3-16 - knowledge that insulin is needed after meals and that the electrical therapy causes release of insulin).

36. In regards to claims 83-84, the apparatus further comprises an automatic glucose sensor to detect a need for an acute insulin response (col. 7, lines 35-40).

37. In regards to claims 103, 104, and 109, the circuitry electrifies the electrode at 5 Hz with a pulse width of less than 30ms (Tables I and II).

38. In regards to claim 107, the electrode is electrified in synchrony with the electrical activity of the stomach (blood glucose rises with the electrical activity of the stomach associated with digestion). Further, this activity "corresponds" to the propagation of action potentials because the activity is caused by action potentials, whether intrinsic or invoked by therapy. Nothing has been set forth to actually sense action potentials.

39. In regards to claim 108, the apparatus reduces high blood glucose levels, but does not reduce normal blood glucose levels (col. 7, lines 30-68).

40. In regards to claims 79-81, 85, 101, 102, 105, 108, 109, 112, 120, and 121, Wernicke discloses circuitry that electrifies electrodes with a frequency, pulse width, amplitude, and other signal parameters (Table I) disclosed by Applicant at pages 44-48 to be effective in producing the claimed results. As such, Wernicke's circuitry necessarily produces the claimed field, regardless of whether these properties were recognized at the time.

41. In regards to claim 114, the electrode is a bipolar electrode mounted to a lead (col. 10, lines 33-35).

42. In regards to claims 115 and 122, the circuitry includes an input to indicate digestion (col. 8, lines 3-16) and electrifies the electrode for at least 15 minutes in response during digestion (Tables I and II).

43. In regards to claim 123, the electrode is electrified with a frequency of 50-150 Hz (Tables I and II).

44. Claims 52, 55, 79-82, 85, 87, 101-112, 114, 115, and 120-123 are rejected under 35 U.S.C. 102(e) as being anticipated by Marchal et al. (US 7,076,306, hereinafter "Marchal").

45. In regards to claims 52, 87, 106, 110, and 111, Marchal discloses an implantable electrode configured to be mounted to a muscle tissue in the abdominal cavity (col. 5, lines 2-4) and circuitry that electrifies the electrode in a manner suitable for blood glucose control (col. 3, lines 12-20). Further, Marchal's electrode is necessarily capable of being mounted attached to a duodenum by, *e.g.*, suturing the electrode in place, as disclosed by Applicant on pages 56 and 57 of the specification becasue the material properties of the stomach and duodenum are similarly conducive to electrode attachment by, *e.g.*, suturing. Marchal further discloses that the circuitry delivers a pulse train with a pulse width of 1 ms and a train shorter than 20 s (col. 5, lines 29-30 and col. 8, line 8).

46. In regards to claim 55, the system is open-loop (Fig. 8a).

47. In regards to claim 82, the apparatus is programmed with information pertaining to slow acting chemical-based insulin therapy provided to a pancreas (col. 3, lines 21-40).

48. In regards to claims 103, 104, and 109, the device provides a frequency of 5 Hz and pulse width of 30 ms (col. 5, lines 19-45).

49. In regards to claim 107, the circuitry is electrified in synchrony with the propagation of action potentials in the stomach (col. 6, lines 11-14).

50. In regards to claims 79-81, 85, 101, 102, 105, 108, 112, 120, and 121, Marchal discloses circuitry that electrifies electrodes with a frequency, pulse width, amplitude, and other signal parameters (col. 5, lines 20-58) disclosed by Applicant at pages 44-48 to be effective in producing the claimed results. As such, Marchal's circuitry necessarily produces the claimed field, regardless of whether these properties were recognized at the time.

51. In regards to claim 114, the electrode is a bipolar electrode mounted to a lead (col. 4, lines 54-67).

52. In regards to claims 115 and 122, the circuitry includes an input to indicate digestion (col. 6, lines 5-10) and electrifies the electrode for at least 15 minutes in response during digestion (Figs. 10a and 10b).

53. In regards to claim 123, the electrode is electrified with a frequency of 50-150 Hz (col. 5, line 27).

Claim Rejections - 35 USC § 103

54. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

55. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

56. Claims 53, 54, 83, and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchal in view of Wernicke. Marchal discloses the essential features of the claimed invention including closed-loop control (col. 6, lines 17-34), but does not expressly disclose circuitry configured to stimulate more than necessary for achieving a desired effect of electrification when the sensed effect does not indicate with certainty that the electrification was sufficient or insufficient, a semi-open loop system, or an automatic glucose sensor for detecting a situation requiring an acute insulin response. However, Wernicke teaches a pancreatic stimulation system comprising circuitry configured to stimulate more than necessary for achieving a desired effect of electrification when the sensed effect does not indicate with certainty that the electrification was sufficient or insufficient (col. 7, lines 30-67), a semi-open loop system (col. 9, lines 41-50), and an automatic glucose sensor for detecting a situation requiring an acute insulin response (col. 7, lines 35-40) to provide the predictable results of accurately keeping the blood glucose levels within acceptable limits.

57. Claims 113 and 116-119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchal (or Wernicke). Marchal (or Wernicke) disclose the essential features of the claimed invention including a sensor to detect the beginning of digestion

(see above) and circuitry that applies the claimed signal parameters (see above) and thus produce the claimed effects (see above), but does not disclose a sensor that detects action potentials in the stomach or an electrode that is sutured to muscle. However, it is well known in the art to provide gastric stimulators with a sensor that detects action potentials in the stomach to provide the predictable result of providing therapy only when needed, and electrodes that are sutured to provide the predictable result of rigid and long-lasting attachment of electrodes. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Marchal (or Wernicke) by providing the gastric stimulator with a sensor that detects action potentials in the stomach to provide the predictable result of providing therapy only when needed, and electrodes that are sutured to provide the predictable result of rigid and long-lasting attachment of electrodes. Please note that, regarding claim 116, it would be obvious to provide a device that provides at least 5 detections over its lifetime (which would read on the claim) to provide the predictable results of avoiding replacement after each detection.

Double Patenting

58. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

59. Claims 52-55, 79-85, 87, and 101-123 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-13, 23-30, and 66 of Application No. 10/570,576 in view of Wernicke or Marchal. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are more narrow in scope than (anticipate) the claims of the instant application, except for the broader limitation of a field that controls a level of pancreas secretion OR a blood glucose level. However, Wernicke and Marchal each individually teach that it is well known in the art to apply an electric field to the pancreas to control blood glucose levels to provide the predictable results of treating diabetes or hypoglycemia. Therefore, this modification would have been an obvious expedient.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

60. Applicant's arguments filed 9/25/2008 have been fully considered but they are not persuasive. In regards to claim 53, the examiner has attempted to clarify the issues of the previous rejection, which hopefully also address the new claim language as well.

It appears that the root of the § 112 issues with this claim arise from the vague "desired" and "certainty" limitations, which are not supported in the disclosure, are unclear, and not enabled. It is unknown/unclear who or what "desires" the values, and how the system determines "certainty."

61. In regards to the art rejections, generally, the examiner would like to respectfully point out that all claims are apparatus claims. As such, intended uses (such as placement of an electrode) does not necessarily differentiate a claimed apparatus from the prior art. For instance, claim 1 requires an electrode *capable of* attachment to muscle tissue. The examiner asserts that both Marchal and Wernicke possess this capability because both are implantable electrodes suitable for placement in the abdominal cavity. Furthermore, the claim recites an apparatus with circuitry that electrifies an electrode in a manner producing various results. Applicant has disclosed certain signal parameters producing these results on pages 44-48. Since the prior art's circuitry also electrifies an electrode with these signal parameters, the prior art must also produce those effects, regardless of whether the respective inventors recognized it at the time. Although structure can be implied from functional recitations, the claimed apparatus must be structurally distinct from the prior art to be patentable.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Familoni (US 5,861,014) is one of many teachings of providing sensors to detect action potentials in the digestive system, and Wernicke et al. (US 5,231,988) is one of many teachings of attaching electrodes by suture.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762